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K091683

4-14, NIHONBASHHONCHO 3-CHOME
CHUO-KU, TOKYO 103-8433 JAPAN

Applicant: Kowa Company, Ltd.

4-14, Nihonbashi-honcho 3-chome

Chuo-ku, Tokyo 103-8433 Japan

Contact: Akihiro Fujita

Date Summary Prepared: May 15, 2009

Device Trade Name: KOWA VX-10α

Classification name: Camera, Ophthalmic, AC-powered

Product code: HKI

Intended use:

The KOWA VX-10α is intended for taking pictures of fundus images with mydriatic or without mydriatic.

Comparison:

The KOWA VX-10i was chosen as the predicate device.

The KOWA VX-10α is a simplified version of the predicate device [KOWA VX-10i (k062021)] by removing the indocyanine green (ICG) angiography mode, removing the use of Polaroid film as a recording media, and changing the availability of the data card for writing patient information as an optional accessory. In addition the lens coating was changed.

In order to evaluate the effects of the change of lens coating for any optical hazards, the following tests were performed:

1. Test Report for ISO10940, 1998: Ophthalmic instruments - Fundus cameras

2. Test Report for ISO 15004-1, 2006: Ophthalmic instruments-Fundamental requirements and test methods Part 1: General requirements applicable to all ophthalmic instruments

3. Test report for ISO 15004-2:2007 Ophthalmic instruments-Fundamental requirements and test methods Part 2: Light hazard protection

The test results demonstrated that the KOWA VX-10α conforms to the above listed standards, which confirmed that the change in the lens coating did not raise any safety concerns. The test results are included in Appendix D.

A comparison of the KOWA VX-10α and the predicate device is shown below in Table B.

Table A. Predicate device

Predicate Device	Manufacturer	510(k) Number	Date Cleared
KOWA VX-10i	KOWA Company Ltd.	K062021	Nov. 1, 2006

Conclusion:
The KOWA VX-10α is equipped with the same fundamental technology features equivalent to the predicate devices, and also delivers the equivalent level safety and effectiveness. Therefore since there are no significant difference in the basic function, safety and effectiveness between the KOWA VX-10α and the predicate device, KOWA concludes that the KOWA VX-10α is substantially equivalent to the KOWA VX-10i (k062021).

Table B. Comparison table

	Proposed Device	Predicate Device
	KOWA VX-10α	KOWA VX-10i (K062021)
Indications For Use	Same	Take pictures of fundus images with or without mydriatic.
Picture magnifications	Mydriatic : 50°/ 30° Non-mydriatic : 45°/ 27°	Mydriatic : 50°/ 30° Non-mydriatic : 45°/ 27°
Photography mode	Non-mydriatic Mydriatic color Fluorescein angiography	Non-mydriatic Mydriatic color Fluorescein angiography Indocyanine Green angiography
Working distance	Same	39 mm
CCD camera for observation	Same	Monochrome CCD
Record media	35mm film	35mm film / Polaroid film
Video camera connect ability	Yes	Yes
Observation system	Same	Mydriatic : Finder Non-mydriatic : LCD
Dioptric compensation	Same	-32D ～ +35D
Focusing	Same	By aligning the split lines
Filter for FA	Present	Present
Filter for ICG	Not applicable	Present
Observation Light Source	Same	Halogen lamp 100W
Photographing Light Source	Same	Xenon flash lamp 300WS
Power consumption	Same	180VA 1800VA (Instantaneous)
Dimension	Same	400(W) x 520(D) x 752(H) mm
Weight	35.5 kg with power unit	35.5 kg with power unit

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kowa Company, Ltd.
c/o Akihiro Fujita, General Manager
Electronics and Optics Division
4-14, Nihonbashi-honcho 3-chrome
Chuo-ku, Tokyo
Japan 103-8433

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Re: K091683
Trade/Device Name: Kowa VX-10a Fundus Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI
Dated: May 15, 2009
Received: June 10, 2009

Dear Mr. Fujita:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K091683

Device Name: KOWA VX-10α

Indication For Use:

The KOWA VX-10α is intended for taking pictures of fundus images with mydriatic or without mydriatic.

Prescription Use ✓ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091683